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CCN #: 004044

June 15, 1999

Dear Dr. Gibbs:

TWRS Privatization Contract No. DE-AC06-96RL13308 - W375 - AUTHORIZATION BASIS AMENDMENT REQUEST REGARDING IDENTIFICATION OF CONFIGURATION MANAGEMENT SUB-ORDINATE STANDARD ADDITIONAL INFORMATION

Reference: CCN# 003192, Letter from D. W. Edwards to Dr. D. Clark Gibbs, DOE/RL, "Authorization Basis Amendment Request regarding Identification of Configuration Request regarding Identification of Configuration Management Sub-Ordinate Standards" dated May 17, 1999.

In working level meetings held subsequent to transmittal of the above Reference, members of your staff requested additional information on the selection of ISP 10007 as an Implementing Standard for Configuration Management. The requested information is attached as a Safety Implementation Note. The Safety Implementation Note documents the application of the 0004 process, describes the necessary tailoring required to implement ISO 10007 consistent with the Authorization Basis, and compares ISO 10007 against the ISMP Sections currently cited as Implementing Standards for Configuration Management.

If you have any questions or we can be of further assistance, please contact Don Edwards at (509) 371-3741 or Dennis Klein (509) 371-3743.

Yours sincerely,

A. J. Dobson
Head of Operations and Safety
BNFL Inc.

PPL/jca

Attachment: Safety Implementation Note (SIN-W375-99-00023)

cc:

Allen, B. T. w/a	BNFL Inc.	MPF-B128
Barr, R. w/a	DOE/RL	A4-70
Brown, N. w/a	DOE/RL	A0-21
Dobson, A. J. w/a	BNFL Inc.	MPF-A117
Edwards, D. W. w/a	BNFL Inc.	MPF-B140
Fish, M. w/a	BNFL Inc.	MPF-B221
Hawkins, A. w/a	DOE/RL	A4-70
Kalman, G. w/a	DOE/RL	A4-70
Landry, W. w/a	BNFL Inc.	Fairfax
Lawrence, M. J. w/a	BNFL Inc.	MPF-A110
Lowry, P. P. w/a	BNFL Inc.	MPF-B111
Morgan, S. w/a	BNFL Inc.	MPF-A116
PDC w/a	BNFL Inc.	ETC-1, Rm. 29
Rasmussen, P. w/a	DOE/RL	A7-80
Smyser, L. w/a	PNNL	A0-21
Tooze, R. w/a	BNFL Inc.	Fairfax
Trautner, L. w/a	BNFL Inc.	MPF-A217



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SIN Number:	SIN-W375-99-00023	Rev.	3
Area:	All	System:	N/A
Subject:	Identification of Implementing Standard for Configuration Management		
Originator:	M. A. Fish <i>George Blunt for</i>	Date:	June 9, 1999
Technical Review:	P.P. Lowry <i>P.P. Lowry</i>	Date:	June 10, 1999

This Safety Implementation Note transmits the results of the BNFL standards selection process (SRD Volume II Appendix A) as applied to the identification of an Implementing Standard for Configuration Management for Safety Criteria 4.0-1, 4.0-2, and 4.0-3. The selected Standard is ISO 10007 *Quality Management - Guidelines for Configuration Management*, (1995).

The standards identification process was carried out by a multi-disciplined team consisting of:

Mike Fish, Lead	Configuration Management Manager
Pete Lowry,	Safety and Regulatory Programs
T. Maciua	Quality Assurance
Graham Sillito	Project Operations
Dave Simpson	Balance of Facilities

Attachment A lists the standards formally reviewed under this process. Attachment B to this note documents the standards identification process and will be used to support an Authorization Basis Amendment Request against the Safety Requirements Document. Attachment C identifies the tailoring required to adapt ISO 10007 as a standard for TWRS-P. Attachment D summarizes how the ISO 10007 Standard when implemented will provided an equivalent level of protection as currently described in the ISMP Sections used as Implementing Standards for Configuration management.

Distribution:	R. Barrington w/a	D. Edwards w/a	E. Hughes w/a
	D. Klein w/a	P. Lowry w/a	T. Maciua w/a
	G. Sillito w/a	D. Simpson w/a	

ISSUED BY
TWRS-P POC
Dea WIS/GA
DATE



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Attachment A – Configuration Management Documents Reviewed

DOE Order 4700.1, Change 1 *Project Management System, Chapter III Project Execution and Control, Part C Configuration Management*, U.S. Department of Energy, June 2, 1992.

EIA-649 (ANSI/EIA-649-1998), National Consensus Standard for Configuration Management, Electronic Industries Alliance, August 1998

ISO 10007 *Quality Management – Guidelines for Configuration Management*, International Organization for Standardization, 1995

MIL-STD-973, *Configuration Management*, U.S. Department of Defense, Change Notice 1, 2, and 3.

NIRMA TG19-1996, *Configuration Management of Nuclear Facilities*, Nuclear Information and Records Management Association Inc., 1996

NUREG/CR—5147, *Fundamental Attributes of a Practical Configuration Management Program for Nuclear Plant Design Control*, U.S. Nuclear Regulatory Commission, June 1988

Application of the DOE/RL-96-0004 Process to the Identification of a Configuration Management Sub-Ordinate Standard**1.0 Purpose**

This white paper documents the application of DOE/RL-96-0004, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, Revision 1, July 1998 to the Identification of a Configuration Management Implementing Standard.

2.0 Tailoring

This application of the 0004 process is tailored to the identification of a programmatic topic. For this topic, the incident hazard is the loss of configuration control over Important to Safety SSCs and facility configuration. Such a loss of control is unacceptable and violates the SRD and DOE Top Level Principles; as such, no further development of the hazard or consequence of the hazard is deemed necessary.

Selection of standards is performed in a manner cognizant of the contractual requirements.

3.0 Applicable Requirements

The requirements listed below are relevant to a discussion of the Configuration Management Implementing Standard.

3.1 BNFL SRD**Safety Criterion 4.0-1**

Formal configuration management shall be applied to all facility activities through deactivation of the TWRS-P facility to ensure that programmatic objectives, including safety, are fully achieved. Work shall be performed and controlled according to pre-approved plans and procedures that clearly delineate responsibility. Documented records shall be retained.

Safety Criterion 4.0 - 2

Written procedures shall be established and implemented to manage changes (except for "replacements in kind") to process chemicals, technology, equipment, and procedures; and, changes to facilities that affect a covered process. The procedures shall assure that the following considerations are addressed before any change:

- (1) The technical basis for the proposed change;*
- (2) Affect of change on safety and health;*
- (3) Modifications to operating procedures;*
- (4) Necessary time period for the change; and,*
- (5) Authorization requirements for the proposed change.*

Employees involved in operating a process and maintenance and subcontract employees whose job tasks will be affected by a change in the process shall be informed of, and trained in, the change prior to start-up of the process or affected part of the process. If a change covered by this paragraph results in a change in the process safety information, such information shall be updated accordingly. If a change covered by this paragraph results in a change in operating procedures or practices, such procedures or practices shall be updated accordingly.

Safety Criterion 4.0-3

A system shall be used to control and maintain accurate as-built records for Important-to-Safety SSCs through deactivation of the facility.

Safety Criterion 7.0-3

The operating organizations shall become and remain familiar with the features and limitations of components included in the design of the facility. They shall obtain appropriate input from the design organization on pre-operational testing, operating procedures, and the planning and conduct of training.

This Safety Criterion (SC 7.0-3) will reference appropriate Implementing Standards for Startup and Operations once identified through the -0004 process.

3.2 Top level Standards:**DOE/RL-96-0006 4.1.5.1 Formal Configuration Management**

Formal configuration management should be applied to all facility activities during the program's lifetime to ensure that programmatic objectives, including safety, are fully achieved. Work should be performed and controlled according to pre-approved plans and procedures that clearly delineate responsibilities. Documented records should be retained.

DOE/RL-96-0006 4.1.5.2 Contractor Design Knowledge

The Contractor operating organizations should become and remain familiar with the features and limitations of components included in the design of the facility. They should obtain appropriate input from the design organization on pre-operational testing, operating procedures, and the planning and conduct of training.

DOE/RL-96-0006 4.1.5.3 Design Documentation

A system should be used to control and maintain accurate as-built drawings during the life of the facility.

DOE/RL-96-0006 5.2.9 Management of Change

The Contractor should evaluate all planned changes involving the technology of the process and the facility design and operation in order to ensure that the impact on safety is analyzed and acceptable and to determine the need for modifications to operating procedures. The Contractor should establish and implement written procedures to manage changes to process chemicals, technology, equipment, and procedures; and changes to facilities. These procedures should address the technical basis for the proposed changes, impact of the changes on process safety, modification of the operating procedures, the schedule for proposed changes, and authorization for proposed changes.

4.0 DOE/RL-96-0004 Process Application

SRD Volume II, Appendix A contains BNFL Inc.'s *Implementing Standard for Safety Standards and Requirements Identification*. This Implementing Standard complies with DOE/RL-96-0004, Table 1, *Process to Develop Standards*, and describes the actions required to apply the process to the selection of standards. The applications of these process steps are tailored as detailed below in relation to the selection of the Implementing Standard for Configuration Management.

Process Documentation

Process Step	Discussion
Process Initiation	Identify staff from Engineering, Safety, and Operations to participate in the Standard Selection Process.
Identification of Work	Design, construct, and operate the TWRS-P facility in compliance with BNFL SRD and all applicable laws, regulations and contract requirements.
Hazards Evaluation	Loss of configuration control over Important to Safety SSCs and facility configuration
Control Strategies	Provide for a formal Configuration Management Program
Identification of Standards	<p>ISO 10007, Quality management – Guidelines for configuration management has been selected as the TWRS-P implementing standard for CM for the following reasons:</p> <p>1) It is an internationally recognized standard for CM and satisfies the requirements of DOE/RL-96-0006, Rev 0 "Top-level radiological, nuclear, and process safety standards and principles for TWRS privatization contractors". Section 4.1.5 "Configuration management" and Section 5.2.9 "Management of Change".</p> <p>It is noted that Section 4.1.5.2 "Contractor Design Knowledge" (Safety Criterion 7.0-3) is not referenced in the ISO 10007. However the BNFL Inc design/construction/startup process with integrated design/operational teams will ensure that: "contractor operating organizations should become and remain familiar with the features and limitations of components included in the design of the facility. They should obtain appropriate input from design organizations on pre-operational testing, operating procedures and the planning and conduct of operations". This will be addressed when the appropriate Operational Readiness Review standards and standards related to conduct of operations are identified prior to the Construction Authorization Request submittal."</p>

<i>Identification of Standards (cont.)</i>	<p>2) The application of a CM program based on ISO 10007 will also satisfy the CM requirements contained in the following TWRS-P documents/sections</p> <ul style="list-style-type: none"> • Integrated Safety Management Plan (ISMP) Section 1.3.16 "Configuration Management", Section 5.3, "Configuration Management" and chapter 8.0 "Document Control and Maintenance". • Initial Safety Analysis Report (ISAR) Section 3.1 "Configuration Management". • Safety Requirements Document Chapter 4, Safety Criterion 4.0-1, 4.0-2, and 4.0-3. • Quality Assurance and Implementation Plan Section 6.2.1 "Design Principles", and Section 6.2.5 "Configuration Management". <p>3) ISO 10007 is clearly and concisely written and addresses the complete life cycle of a project (product) and therefore is applicable to all phases of the TWRS-P project from design start to deactivation. The standard also uses generally accepted CM terminology and concepts, which will aid understanding and training on the project.</p>
<i>Confirmation of Standards</i>	<p>Confirmation of standards is completed through internal review. On completion of review, standards meet the following criteria:</p> <ul style="list-style-type: none"> • Standards are relevant to proposed usage. • Standards represent current industry guidance on particular topic. • Application of the standard does not conflict with TWRS-P contract, state or federal requirements. <p>Included in this review is Project Safety Committee review and recommendation of acceptance for the standard.</p>
<i>Formal Documentation Recommendation by CR</i>	<p>Formal documentation consists of internal BNFL Inc. Safety Implementation Note describing the 0004 process application and a formal Authorization Basis Amendment Request submitted to the RU describing changes to the Safety Requirements Document</p> <p>The Contractor Representative (CR) certifies that the submittal is adequate and transmits to the Director of the Regulatory Unit</p>



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Attachment C – Tailoring of ISO 10007

The following discussion addresses the tailoring of ISO 10007 for use by BNFL as an Implementing Standard for Configuration Management.

Page 1, Section 1 Scope.

Second paragraph, last sentence. Replace this sentence with:

"For TWRS-P ISO 10007 amplifies on the configuration management elements found in the Quality Assurance Plan Implementation Plan, BNFL-5193-QAP-01."

Justification: For TWRS-P the approved QAP defines the quality management and quality system elements.

Page 1, Section 2 Normative references.

Delete reference to the ISO 10011 series of standards.

Justification: As discussed for Section 8, for TWRS-P the approved QAP defines the principles, criteria, and practices for the configuration management system audit.

Page 7, Section 7.7 Configuration management plan (CMP)

Delete second paragraph

Justification: This paragraph addresses activities outside BNFL Inc. workscope or control (i.e., multiple projects, multi-level contracts, and customer configuration management plans).

Page 8, Section 8 Configuration management system audit

Revise the last paragraph to read:

"Principles, criteria, and practices of the CM system audit should comply to the TWRS-P QAPIP."

Justification: For TWRS-P the approved QAP defines the principles, criteria, and practices for the conduct of audits and self-assessments.

Page 11 and 12 Annex B

Delete.

Justification: Although provided only as information, as noted in Section 1 above, the ISO 9000 Series of Standards are not being implemented at TWRS-P and this Annex is therefore removed to reduce potential confusion to non-applicable cross references.



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Attachment D – Comparison to Previously Cited ISMP References

SUMMARY EVALUATION:

The Configuration Management Program described within ISO 10007 addresses all attributes within the ISMP Sections cited as Implementing Standards for the noted Safety Criteria. The ISMP Sections include additional detail relative to responsibilities for conduct of the CM related processes which is included with Section 6 of ISO 10007 Organization of configuration management. Additional detail on implementation of the CM program outlined in ISO 10007 will be included in the Configuration Management Plan and PSAR.

The following discussion describes how ISO 10007 addresses the commitments contained in the individual ISMP Sections cited as Implementing Standards for CM related SRD Safety Criteria.

Safety Criterion: 4.0 - 1

Formal configuration management shall be applied to all facility activities through deactivation of the TWRS-P facility to ensure that programmatic objectives, including safety, are fully achieved. Work shall be performed and controlled according to pre-approved plans and procedures that clearly delineate responsibility. Documented records shall be retained.

Safety Criterion 4.0-2

Written procedures shall be established and implemented to manage changes (except for "replacements in kind") to process chemicals, technology, equipment, and procedures; and, changes to facilities that affect a covered process. The procedures shall assure that the following considerations are addressed prior to any change:

- (1) The technical basis for the proposed change;
- (2) Impact of change on safety and health;
- (3) Modifications to operating procedures;
- (4) Necessary time period for the change; and,
- (5) Authorization requirements for the proposed change.

Employees involved in operating a process and maintenance and subcontract employees whose job tasks will be affected by a change in the process shall be informed of, and trained in, the change prior to start-up of the process or affected part of the process. If a change covered by this paragraph results in a change in the process safety information, such information shall be updated accordingly. If a change covered by this paragraph results in a change in operating procedures or practices, such procedures or practices shall be updated accordingly.

Safety Criterion 4.0-3

A system shall be used to control and maintain accurate as-built records for Important to Safety SSCs through deactivation of the facility.



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ISMP Section 1.3.16 Configuration Management cited as an Implementing Standard for Safety Criteria 4.0-3 (also cited in SC 4.1-2 and 4.5-17, however, these SC will be evaluated separately by subsequent ABAR(s)).

Paragraph 1. Defines the need for a configuration management program during design, construction, operation and deactivation. Assigns the responsibilities for implementation of configuration management.

ISO 10007 states CM is applicable to the lifecycle of the product (facility) and identifies that configuration documents should be controlled. ISO 10007 Section 6 requires the CM structure to be defined and includes required interface between subcontractors and vendors and assignment of responsibilities to appropriate authorities.

Paragraph 2. Requires review of changes to the facility, programs, procedures prior to implementation and includes control of the AB.

ISO 10007 Section 5.3 and 7.4 contain the requirements to evaluate proposed changes. Control of the AB is subject to the process as defined in RL/REG 97-13 (contractual requirement) in addition to the CM process.

Paragraph 3 describes the BNFL process (Design Change Application) to ensure changes are identified, communicated, recorded, and controlled.

As addressed above, ISO 10007 Section 5.3 and 7.4 contain the requirements to evaluate proposed changes, which includes identification of items impacted, and recommends the use of standard forms to document the steps of the change process.

Paragraph 5 describes rationale for needing a CM process. No commitment made.

Paragraph 6 describes four basic steps of a CM program. [Identification, Evaluation, Approval and Implementation]

ISO 10007 Section 7.4 requires the CM program to address the same attributes.

7.4.1 Identification and documentation of the need for change

7.4.2 Evaluation of change

7.4.3 Approval of change

7.4.4 Implementation and verification of change

Paragraphs 6 and 7 (Table 1-4) identify the TWRS-P organizations responsible for reviewing changes.



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As discussed above, ISO 10007 requires changes to be reviewed and requires the organizational structure of the CM program and relationships between the CM function and interfacing organizations be defined.

Paragraph 8 (page 1-34) discusses types of changes expected. No commitments identified.

Paragraph 9 defines the objective of the CM program and identifies further detail regarding the CM program description.

ISO 10007 Section 4.1 describes the programmatic objective of CM. Further detail on the CM program will be included in the PSAR and the Configuration Management Program Plan.

Section 5.3 Configuration Management cited as an Implementing Standard for Safety Criteria 4.0-1, 4.0-2 and 4.0-3 (also cited in SC 4.1-2, 4.4-1, 4.4-2, 7.2-7, and 7.6-4, however, these SC will be evaluated separately by subsequent ABAR(s)).

Paragraph 1 requires that the CM program be proceduralized and address the listed 11 items.

ISO 10007 requires written procedures to describe company policies, activities and conventions related to the CM process. For Items 1, 2, 7 and 10 RL/REG 97-13 is the contractually mandated process for Authorization Basis Changes. ISO 10007 7.4.1 requires the CM program to address the need for the change (item 3), Section 7.4.2 requires the evaluation of the impacts of the change (items 4, 5, 6, 9 and 11), Section 7.4.3 defines approval authority for changes (item 7) and Section 7.4.4 requires consequential actions be carried out (items 8, 9, and 11)

Paragraph 2 states that the PSM required management of change procedures is addressed within the BNFL CM program. No commitment relative the above Safety Criteria identified.

Paragraph 3 identifies further detail regarding the CM program description.

Further detail on the CM program will be included in the PSAR and the Configuration Management Program Plan.

Paragraph 4 describes attributes relative to Safety Design Class and Safety Design Significant SSCS which will be included as part of the CM program documentation.

ISO 10007 Section 5.2.2 Requires the necessary functional and physical characteristics of a configuration item be clearly identified. This paragraph will be revisited subject to a review of the Implementing Standard for Safety Criterion 4.4.-1.

Paragraph 5 describes part of the approval process for CM changes.



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For CM changes affecting the AB the contractually mandated RL/REG 97-13 process will be used. ISO 10007 Section 7.4.3 requires authorized persons review and approve changes.

Section 5.6.1 Procedures cited as an Implementing Standard for Safety Criterion 4.0-1, (also cited in 7.0-1, 7.2-5, 7.2-6, and 7.2-7, however, these SC will be evaluated separately by subsequent ABAR(s)).

All Paragraphs. This section describes the development and requirement for use of approved procedures. ISO 10007 requires written procedures to describe company policies, activities and conventions related to the CM process.

Section 8.0 Document control and Maintenance cited as an Implementing Standard for Safety Criteria 4.0-1 and 4.0-3 (also cited in 3.1-8, 7.2-4, 7.3-4, 7.3-10, 7.7-2, 7.8-1 9.1-5, 9.2-6, and 9.2-6, however, these SC will be evaluated separately by subsequent ABAR(s)).

Paragraph 1 addresses quality assurance requirements for records management. No commitment relative the above Safety Criteria identified.

Paragraph 2 addresses document preparation, review, approval, issuance and revision and cites examples of safety documents developed a part of the safety management process.

ISO 10007 (Section 4.1) identifies that the CM program is applicable to hardware, software, processed material, services and related technical documentation. Thus the items as described in Section 8.0 would be included under the CM program.

BNFL Inc. agrees that standards are not uniform in their terminology. Therefore, BNFL Inc. will use the above rules in future Authorization Basis Amendment Request submittals to identify what portions of a proposed standard BNFL Inc. considers commitment and what portions BNFL Inc. considers optional. This methodology provides a default rule for each type of declarative statement in a standard. As a result, it should be easier for BNFL Inc. and the Regulatory Unit to differentiate between commitments and options.

Should you have any questions or comments, please call me at (509) 371-3589 or Mr. Don Edwards at (509) 371-3741.

Yours sincerely,



A. J. Dobson
Manager, Operations and Safety
BNFL Inc.

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PDC	BNFL Inc.	K110
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